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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,328	BARRAS ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *32-35,46-68,72 and 73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31,36-45 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *26 March 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-73 are presented for examination.

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(a-d) to United Kingdom Patent Application No. GB 0224909.2, filed October 25, 2002. Applicant's Information Disclosure Statement (IDS) filed March 26, 2004 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (two pages total), the Examiner has considered the cited references. Applicant's response filed January 9, 2006 to the requirement for restriction dated December 5, 2005 has also been received and entered into the application.

Requirement for Restriction/Election

Applicant's election **with traverse** of the invention of Group I (claims 1-31, 36-45 and 69-71), drawn to dry compositions for admixture with water comprising polyethylene glycol, ascorbic acid, an alkali metal or alkaline earth metal sulphate and, optionally, one or more electrolytes, and kits or preparations thereof, in the reply filed January 9, 2006, is acknowledged. Applicant's traversal is on the grounds that the Examiner has directly ignored the limitations of the claims in order to show patentable distinction between the product and its process of use. Applicant further submits that a search of the art relevant to Group I will reveal all of the art relevant to Group II and that the classification of each group is identical, thus, indicating that examination of all claims together would be more efficient and less burdensome.

Applicant's traversal has been carefully considered, but fails to be persuasive in establishing error in the propriety of the present restriction requirement.

First, while Applicant asserts that the Examiner has directly ignored the limitations of the claims in order to show patentable distinction between the product and its process of use, Applicant's attention is directed to pages 2-3 of the previous Office Action dated December 5, 2005, which sets forth the present requirement for restriction, where it states:

"In the instant case, the methods of cleansing the colon of a mammal may be accomplished using any one or more of the known, conventional type therapies in the art, including: (i) traditional laxative compound; (ii) enemas, such as those containing sodium phosphate or mineral oil; (iii) orthostatic intestinal lavage using an electrolyte solution; or (iv) a solution of magnesium citrate and sodium picosulphate, among others.

Furthermore, the composition containing polyethylene glycol, ascorbic acid, an alkali metal or alkaline earth metal sulphate and, optionally, one or more electrolytes, may also be used in a materially different process of using such compounds. In particular, such a composition may be used as gels or liquids for rehydration following intense periods of exercise or bodily stress resulting in significant water loss."

Applicant has not fully considered the entire rationale behind holding the presently claimed inventions patentably distinct. While it would be incorrect to establish patentable distinction based only on the fact that the method may be achieved using different products, since the method expressly requires the presently claimed product to be used, such was not the sole reasoning given for holding patentable distinction. In fact, as repeated above, patentable distinction was demonstrated by a showing that the presently claimed composition could be used in materially different processes. Thus, for these reasons, Applicant's traversal is not persuasive because the inventions are properly held to be distinct.

In addition, Applicant is reminded that compositions of matter are examined based upon their physical components and structural form, not the intended use of such a compound. In light of such, due to the variety of vastly different uses for the composition that are already known in the prior art, it is clear that a comprehensive search of the compound would necessarily entail a comprehensive search of the prior art well beyond simply those therapeutic methods that Applicant has claimed. As a result, an undue burden would be placed on the Examiner to examine all of the patentably distinct inventions presently claimed.

Consideration of the plurality of inventions that Applicant has claimed would significantly compromise and preclude a quality examination on the merits. Furthermore, execution of a search encompassing the multiple inventions presently claimed would not only constitute an undue burden on the Examiner, but *consideration of the findings* of such a search in accordance with the requirements of the law under 35 U.S.C. §§101, 102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the class and subclass in which it is classified. Thus, regardless of the fact that the presently claimed product may be classified in the same class and subclass as the process of using such a product, it is noted that a comprehensive search of the copious amounts of patent and non-patent literature for each of the presently claimed inventions would necessarily place an undue burden on the Examiner for the reasons already described above.

Therefore, for the reasons above and those made of record at pages 2-4 of the previous Office Action dated December 5, 2005, the restriction requirement is deemed proper and is made **FINAL**.

Claims 32-35, 46-68 and 72-73 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b), as being to non-elected inventions, there being no allowable generic or linking claim.

The claims corresponding to the elected subject matter are 1-31, 36-45 and 69-71 and such claims are herein acted on the merits.

Applicant's Claim for Priority under 35 U.S.C. 119(a-d)

Applicant's claim for the benefit of a foreign-filed application (United Kingdom Patent Application No. GB 0224909.2), filed October 25, 2002, under 35 U.S.C. 119(a-d) is acknowledged. Applicant is reminded that the later-filed application must be an application for patent for an invention that has been disclosed in the prior application (i.e., the foreign-filed application). The disclosure of the invention in the foreign application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

However, Applicant has failed to file a certified copy of the UK application as required by 35 U.S.C. 119(b). For this reason, the effective filing date is the actual filing date of the present application (October 24, 2003).

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the limitation "wherein the composition comprises the additional features described in claim 27" renders the scope of the claim indefinite. For example, while claim 27 may be expressly drawn to the additional use of a sweetener component of the composition, claim 27 is dependent upon claim 1 and, thus, incorporates all of the limitations recited therein. As a result, Applicant has not precisely and distinctly set forth without ambiguity whether the recitation "wherein the composition comprises the additional features described in claim 27" is to be limited solely to the addition of a sweetener to the composition, or whether it is meant to indicate the addition of the sweetener and identical active agents and dosages amount thereof as recited in claim 1, from which claim 27 depends. In light of such, it is clear that Applicant has not set accurately set forth the metes and bounds of the subject matter for which he seeks protection.

For these reasons, Applicant has failed to properly define the claimed subject matter in such a way as to reasonably apprise the public of what would constitute infringement of the present claims. The claims, thus, fail to meet the tenor and express requirements of the law under 35 U.S.C. 112, second paragraph and are properly rejected.

For the purposes of examination and the application of prior art, the claim will be interpreted to read simply upon the addition of a sweetening agent to the composition.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31, 36-45 and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borody et al. (WO 89/05659; 1989) in view of Fordtran (WO 87/00754; 1987), Stedman's Medical Dictionary (22nd Edition, 1972; page 737), The Merck Index (Monograph 8723; 1996) and Williford et al. (U.S. Patent No. 5,458,890; 1995).

Borody et al. teaches a colon evacuant for cleansing the gastrointestinal tract (page 1, lines 3-5; see present claims 1-31, 36-45 and 69-71) containing ascorbic acid or a salt thereof

(0.25-50.0 g/L; page 2, lines 18-20 and page 4, line 3; see present claims 1, 19-23, 36 and 39-40), electrolytes (page 3, lines 30-31; see present claims 1 and 36), including sodium chloride (0.5-3.0 g/L; page 3, line 37; see present claims 1, 15-16 and 36), potassium chloride (0.2-2.0 g/L; page 3, line 38; see present claims 1, 17-18 and 36), sodium hydrogen carbonate (0.5-5.0 g/L; page 4, line 1; see present claims 1 and 36) or sodium sulfate (2.0-10.0 g/L; page 4, line 2; see present claims 1, 10-12, 14, 36 and 42), sweetening or flavorings (page 2, lines 25-26 and page 4, lines 5-11), such as aspartame (page 4, line 8; see present claims 26-27) or lemon flavor (page 4, lines 8-9; see present claims 24-25), and a high molecular weight polyethylene glycol (page 3, lines 26-29; see present claims 1, 4-9 and 36), preferably with a weight greater than 2000 (page 3, lines 26-28; see present claim 4), particularly 3000-4500, such as PEG-3350 or PEG-4000 (30-60 g/L; page 3, lines 28-29 and 36; see present claims 5-6), which may be a powdered formulation (page 3, lines 15-16; see present claims 1 and 36) or combined with water to form a solution (page 3, lines 15-16 and page 7, lines 4-7; see present claims 29 and 43), and further which may be provided in sachets or screw top boxes or cartons (page 7, lines 8-11; see present claims 30 and 43), wherein ascorbic acid is packaged separately from the other components (page 2, lines 18-22; see present claims 31, 45 and 70) and wherein the ascorbic acid may be coated with silicone or ethyl cellulose coatings to prevent reaction between the ascorbic acid and other components of the formulation (page 3, lines 21-23; see present claim 28).

The differences between the Borody reference and the presently claimed subject matter lies in that the reference fails to teach:

(i) the particularly claimed dosage amounts, ratios and osmolarity of the active composition (see present claims 1-3, 7-12, 16, 18-20, 22, 36 and 39-40);

(ii) the use of magnesium sulfate, sodium ascorbate or a mixture of ascorbic acid and salts thereof as an active component of the composition (see present claims 1, 13, 19-23, 36 and 39-40);

(iii) the use of the sweeteners acesulfame-K, saccharine or citric acid (see present claim 27); or

(iv) the formulation of the active composition into a kit comprising a box with attached instructions (see claim 71).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Borody discloses a preferable concentration of polyethylene glycol from 30-60 grams per liter, but does not expressly teach that the concentration of polyethylene glycol may be increased greater than 60 grams to, for example, up to 350 grams per liter. However, one of ordinary skill in the art would have been motivated to do so because polyethylene glycol has significant advantages when used in bowel cleansing agents.

In this regard, Fordtran (WO 87/00754; 1987) is cited. Fordtran teaches several important advantages to the use of polyethylene glycol (PEG) in laxative or lavage agents: (1) PEG is poorly absorbed or not absorbed at all in the gastrointestinal tract; (2) PEG is not fermented by colonic bacteria and, therefore, does not metabolize to products that can be absorbed or products that are gaseous; (3) consumption of PEG does not adversely affect the

intestinal mucosa; and (4) there is no rapid increase in intravascular volume and no production of potentially explosive gases (page 5, lines 5-31).

In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art to increase the concentration of polyethylene glycol in the disclosed composition in order to effect a more rapid and thorough cleansing of the colon using a smaller volume of solution and a shorter time to completely cleanse the colon and gastrointestinal tract. Such a person would have been motivated to do because polyethylene glycol was known to not be absorbed in the gastrointestinal tract, thus, allowing for more effective flushing of the colon without any residue; polyethylene glycol was known to be innocuous to the gastrointestinal tract and also that polyethylene glycol is not fermented by colonic bacteria and, therefore, avoids the production of excess gas, which can cause discomfort and danger to the patient, particularly if such gases are potentially explosive and the patient is undergoing a surgical procedure.

The determination of the optimum dosage amounts and ratios of the active components (i.e., ascorbic acid, alkali metal or alkaline earth metal sulfates and electrolytes) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compounds employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage amounts and ratios that would have actually been employed would have varied widely and, in the absence of evidence to the

contrary, the currently claimed specific dosage amounts and ratios are not seen to be inconsistent with those that would have been determined by the skilled artisan.

Though Borody does not expressly teach the claimed osmolarity of the solution as recited in present claims 1-3, it is noted that the osmolarity is directly dependent upon the amount of solute present in the solution. In other words, varying concentrations of solute (i.e., the active agents) will directly affect the osmolarity of the solution. Multiple solutes present in the same solution will also each directly contribute to the overall osmolarity of the solution as a whole. As a result, determination of the optimum dosage amounts and ratios of components would necessarily affect the overall osmolarity of the solution. Thus, just as the dosage amounts and ratios that would have actually been employed would have varied widely and are not seen to be inconsistent with those that would have been determined by the skilled artisan, the resultant osmolarity of the solution would also have directly varied in view of the varying amounts of active agents and is, therefore, also not inconsistent with the optimum osmolarity of the solution that would have been determined by the skilled artisan.

Moreover, it is noted that the skilled artisan would have been further motivated to determine the optimum amounts and ratios of the active agents and, thus, the optimum osmolarity of the composition, in order to preserve the delicate balance of electrolytes and water in the body without causing an undue loss or excess of electrolytes or fluid overload, since such situations may potentially result in renal failure and dysfunction of other essential organs, such as the heart.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to

determine where in a disclosed set of percentage ranges is the optimum combination of percentages...***Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation***." (emphasis added)

(ii) Although Borody is silent as to the particular use of magnesium sulfate in the disclosed composition, the use of such a sulfate salt would have been well within the purview of the skilled artisan because it was well known in the art at the time of the invention that such a salt had a cathartic property that was commonly employed in laxative compositions.

In this regard, Stedman's Medical Dictionary (1972) is cited. Stedman's teaches that magnesium sulfate was used as the active ingredient of most of the natural laxative wafers and is a prompt acting cathartic agent (page 737, col.2).

In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ magnesium sulfate in the composition disclosed by Borody because such a compound would have contributed to the cleansing action of the composition taught by the reference by concomitantly effecting purging of the colon. Motivation to administer magnesium sulfate in conjunction with the composition disclosed by Borody flows logically from the efficacy demonstrated in the prior art for each individual compound being capable of inducing a gastrointestinal cleansing effect. Such a common function of each of the compounds would have raised the reasonable expectation of success that the combination of both magnesium sulfate and the composition taught by Borody would have achieved, at minimum, a potentiated cleansing effect. In the absence of evidence to the contrary, it is generally *prima facie* obvious to use in combination two or more agents that are each known

to separately to share the same function. Please also reference *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

Furthermore, though Borody expressly teaches the use of ascorbic acid or salts thereof but fails to expressly teach the concomitant use of ascorbic acid and salts thereof, the use of both ascorbic acid and its salts together in the disclosed composition would have been *prima facie* obvious to one of ordinary skill in the art. The use of a pharmaceutically acceptable salt of ascorbic acid, particularly a salt well known in the art, such as sodium ascorbate (see The Merck Index, Monograph 8723; 1996), optionally in combination with ascorbic acid in free base form, would have provided additional advantages to the pharmaceutical composition than just using the free base of ascorbic acid alone.

For example, as taught by Remington's Pharmaceutical Sciences, drugs may be formulated into salts to modify the duration of action of a drug; to modify the transportation and distribution of a drug in the body; to reduce toxicity; and to overcome difficulties encountered in pharmaceutical formulation procedures or in the dosage form itself (see column 2 of page 424, first paragraph). Thus, it would have been obvious to the skilled artisan motivated by any one or more of these factors to formulate the ascorbic acid into a pharmaceutically acceptable salt, for use as the sole source of ascorbic acid or for use in conjunction with free base ascorbic acid, in order to enhance the pharmacokinetic parameters of the drug or to reduce the toxicity with the reasonable expectation that the therapeutic benefit of ascorbic acid in salt form would have been the same or substantially similar to that of ascorbic acid itself.

(iii) Borody broadly teaches the use of a sweetening or flavoring agent in the disclosed composition, such as aspartame or lemon flavor. Though Borody does not expressly disclose the

use of acesulfame-K, saccharin or citric acid, the use of such compounds as pharmaceutical flavor additives was well known in the art at the time of the invention.

In this regard, Williford et al. (U.S. Patent No. 5,458,890; 1995) is cited. Williford et al. teaches a variety of flavor additives, including aspartame, acesulfame-K, saccharin or citric acid, for use in pharmaceutical compositions to provide a flavoring or sweetening sensation (col.6, lines 45-67 and col.7, Table 1) to orally delivered products (see abstract, for example).

In light of such a teaching, it would have been well within the purview of the skilled artisan to employ any one or more of acesulfame-K, saccharin or citric acid in the composition disclosed by Borody because each was well known to contribute a sweet or flavorful quality to either food or pharmaceutical products. Such a person would have been motivated to include such an agent in the dry composition disclosed by Borody because any one or more of such additives would have contributed a reasonably pleasant taste to the composition to enhance palatability of and patient compliance with the disclosed composition. Furthermore, each was known to be amenable for use in a pharmaceutical product, which is further motivation that the choice of such a flavoring additive would have been *prima facie* obvious and well within the purview of one of ordinary skill in the art and would not have significantly altered the activity of the composition as a whole.

(iv) With regard to the formulation of claim 71, wherein the colon cleansing formulation comprising a PEG-containing colon cleansing solution is packaged inside a box with instructions for its use, the mere placement of such a formulation into a box would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to facilitate manufacture and dissemination of the

formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen by providing such a formulation in a portable container that can be transported and carried to allow for convenient dosing, as necessary.

Furthermore, the subject matter printed on the label or package insert as instructional means for administering the formulation does not provide for patentable distinction over what would have been suggested by the prior art because such instructions amount to literary work and, thus, are not covered by patent laws, but rather copyright laws. Even if such were covered by patent laws, such subject matter represents no more than a statement of intended use and does not impart any physical or otherwise material limitation to the claimed kit that is either not present in the prior art or made obvious by the teachings of the prior art. It has been held that Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

Conclusion

Rejection of claims 1-31, 36-45 and 69-71 is deemed proper.

Claims 32-35, 46-68 and 72-73 are withdrawn pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

February 15, 2006

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